PB88-112362

Pesticide Assessment Guidelines Subdivision O, Position Documents Effects of Storage (Storage Stability) on Validity of Pesticide Residue Data

(U.S.) Environmental Protection Agency
Washington, DC

Sep 87

U.S. Department of Commerce
National Technical Information Service
NTIS

PB88-112362

A POSITION DOCUMENT OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

EFFECTS OF STORAGE (STORAGE STABILITY) ON VALIDITY OF PESTICIDE RESIDUE DATA

Hazard Evaluation Division
Residue Chemistry Branch

August 1987

REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL
INFORMATION SERVICE
SPRINGFIELD, VA. 22161

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No. PB88 112362/AS
4. Title and Subtitle: Pesticide Assessment Guidelines, Subdivision O, Position Document: Effects of Storage (Storage Stability) on Validity of Pesticide Residue Data			5. Report Date: September 1987 6.
7. Author(s): Residue Chemistry Branch, HED/OPP			8. Performing Organization Rept. No. 540/09-88-002
9. Performing Organization Name and Address: US Environmental Protection Agency Office of Pesticide Programs Hazard Evaluation Division (TS-769C) 401 M Street, SW Washington, D.C. 20460			10. Project/Task/Work Unit No. 11. Contract(C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address: Same as #9			13. Type of Report & Period Covered 14.

15. Supplementary Notes

For further information, refer to Subdivision O: PB83-153981, PB86-203734, PB86-248192, and PB87-208641.

16. Abstract (Limit: 200 words)

The purpose of this document is to alert all participants in the federal pesticide registration and tolerance process of the need to provide adequate data on the possible effects of storage on the magnitude of the residue in commodities during the time between sample collection and sample analysis. This document does not introduce any new data requirements or revisions into the Pesticide Assessment Guidelines-Subdivision O (171-4). It clarifies ambiguities in interpretation of those existing Guidelines and thereby should aid registrants in submitting acceptable data packages on the magnitude of the residue to facilitate the Agency's review process.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement: Publicly Available	19. Security Class (This Report): UNCLASSIFIED	21. No. of Pages: 7
	20. Security Class (This Page): UNCLASSIFIED	22. Price: PCA02/MFA01

(See ANSI-Z39.18) See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

EFFECTS OF STORAGE (STORAGE STABILITY) ON VALIDITY OF PESTICIDE RESIDUE DATA

PURPOSE:

The purpose of this document is to alert all participants in the federal pesticide registration and tolerance process of the need to provide adequate data on the possible effects of storage on the magnitude of the residue in commodities during the time between sample collection and sample analysis. This policy applies to all samples derived from supervised field trials, metabolism and feeding studies; processing studies; and to all magnitude of the residue data submitted to EPA. Lack of adequate storage stability data has become a major factor in delaying registrations of pesticides. New chemicals that are subjected to the EPA screening for acceptability for review will be checked for adequacy of storage stability data.

This document does not introduce any new data requirements or revisions into the Pesticide Assessment Guidelines-Subdivision O (§171-4). It clarifies ambiguities in interpretation of those existing Guidelines and thereby should aid registrants in submitting acceptable data packages on the magnitude of the residue to facilitate the Agency's review process.

BACKGROUND:

Data on the magnitude of the residue for crops, meat, milk, poultry, eggs, fish, and processed commodities are required by 40 CFR §158.125 to support the registration of any pesticide intended for use on a food or feed crop under the amended Federal Insecticide, Fungicide, and Rodenticide Act. These data are also needed to estimate the exposure of the general population to pesticide residues in food, and for establishing tolerances for pesticide residues in or on raw and processed foods or feeds under provisions of Sections 408 and 409, respectively, of the Federal Food, Drug, and Cosmetic Act.

In most cases, treated samples undergo a period of storage (usually frozen) prior to their analyses for pesticide residues. During this time it is possible that residue levels could decline in the matrices of interest - that portion of the plant and/or animal commodities on which pesticide tolerances/exemptions are sought. Therefore, unless samples are quickly analyzed, data will need to be provided by the petitioner/registrant to validate the magnitude of residue levels of pesticides in commodity matrices during such a storage period.

EXPERIMENTAL DESIGN AND TEST PROCEDURES:

The storage stability study should be experimentally designed to answer the following question: Are the parent pesticide and its metabolite(s) that together comprise the "total toxic residue" which is to be regulated stable in the "matrices of interest" during storage? The term "total toxic residue" is used to describe the sum of the parent pesticide and its degradation products, metabolites (free or bound), and impurities that are considered to be of toxicological significance, and therefore warrant regulation.

For unrelated commodities in petition submissions, the petitioner will need to supply supporting storage stability data for the total toxic residue (i.e., for each component specifically expressed in the tolerance) for each commodity. If the analytical method is capable of quantitating each component of the residue individually, then a spiking mixture may be used for fortification purposes. If the analytical method is only capable of measuring the total residue, then the storage stability of each component comprising the total toxic residue is needed.

Storage stability studies with periodic sample analysis should normally be run concurrently with the storage of treated samples. However, in certain situations where pesticides are prone to breakdown or have high volatility, it is advisable to run a storage stability study in advance of the magnitude of the residue study so that proper storage and maximum time of storage can be determined before treated samples are collected and stored. In these cases, storage stability studies should also be run concurrently with the storage of treated samples.

Samples used in storage stability studies should be stored exactly like the field incurred residue samples; e.g., in the same freezer, in the same types of containers, and for the same lengths of time. Deviations from this may result in the treated samples being considered invalid due to lack of appropriate supporting storage stability data.

The use of unblended samples, blended samples, or raw sample extract for a storage stability study is acceptable, provided the supervised trial samples to be used to determine the magnitude of the residue are handled in a similar manner. If samples are stored in more than one of these conditions (ie, some samples blended prior to storage and some samples stored whole), then storage stability data are needed to validate each condition of treated sample storage.

The registrant or petitioner may choose whether to use field incurred residue samples of known value analyzed prior to storage, or to use fortification samples in the storage stability study.

It is always advisable to have extra storage stability samples available to allow for unforeseen delays in analysis, and to verify the results of check sample analysis should it be necessary to reanalyze them for possibly aberrant results.

If limited decline of the residue is shown to occur during the storage period, correction factors may be applied to the supervised trial residue results to determine the appropriate level at which the proposed tolerance should be established. If extensive decline of the residue is shown to occur, storage of supervised trial samples prior to analysis should be avoided. Unless storage stability has been documented previously, the Agency suggests samples be analyzed as soon as possible or within 14 days of collection to avoid storage stability problems. These studies are particularly important when the residue is labile or volatile. For those compounds known to be labile or volatile, storage stability data are even more important. These samples should be analyzed as soon as possible (within several days of collection).

RESIDUE RESULTS:

The petitioner/registrant's report on storage stability studies should include all information necessary to provide a complete and accurate description of the commodities that were stored (whether raw or processed); the test compound(s); the experimental design and storage conditions (e.g., freezer temperature, length of storage, type of containers, etc.); residue methods(s) and instrumentation; storage stability results and reporting of the data; statistical analysis; and quality control measures/precautions taken to ensure the validity of these operations, including the dates for each step above.

After a series of appropriate storage stability studies on unrelated commodities have been submitted that show similar results, future petitions on related commodities can reference previously accepted studies in lieu of conducting additional storage stability studies. Translating a storage stability study from one commodity to another will be considered appropriate only if both commodities are related (e.g., in the same crop group), and if the experimental design is considered appropriate to current considerations.

FOR FURTHER INFORMATION:

The reader is referred to the Agency document, "Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, Series 171-4, Storage Stability Study, Addendum on Data Reporting", which is available from the National Technical Information Service, Springfield, VA [NTIS Document #PB86-248192], for additional details about conducting a storage stability study.

If you have questions regarding this document, the EPA contact is Francis D. Griffith, Jr., Hazard Evaluation Division (TS-769C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, D.C. 20460, telephone (703) 557-7484.